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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/869,333 | 07/26/2001 | Franco Pamparana | 101615-00012 | 5701 |

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| EXAMINER | |
|---|---|
| HENLEY III, RAYMOND J | |
| ART UNIT | PAPER NUMBER |
| 1614 | |

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/869,333 | PAMPARANA, FRANCO | |
| | Examiner | Art Unit | |
| | Raymond J. Henley III | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *12-14,16,18-20,22,24,25,27,28 and 30-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-14,16,18-20,22,24,25,27,28 and 30-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**CLAIMS 12-14, 16, 18-20, 22, 24, 25, 27, 28 AND 30-35 ARE PRESENTED FOR EXAMINATION**

Applicant's "Amendment D" filed March 30, 2005 has been received and entered into the application. Accordingly, claims 12, 18, 24, 27, 31, 32, 34 and 35 have been amended.

In view of the above amendments, the rejection of claims 12-14, 16, 18-20, 22, 24, 27, 28 and 30-35 under 35 U.S.C. § 112, first paragraph, as set forth in the previous Office action dated December 30, 2004 at pages 2-6, is withdrawn.

***Claim Rejection - 35 USC § 103 (New Ground Necessitated by Amendment)***

Claims 12-14, 16, 18-20, 22, 24, 27, 28 and 30-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Breivik et al. (U.S. Patent No. 5,502,077), already of record, in view of Harrison's Principles of Internal Medicine ("Harrison's, newly cited by the Examiner).

Breivik et al. teach fatty acid compositions containing at least 80% by weight of omega-3-fatty acids, salts or derivatives thereof, wherein eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) comprises at least 75% by weight of the total fatty acids (see present claims 12-14, 18-20, 24, 25, 27 and 28 where the EPA and/or DHA content of the mixture may be "greater than 25% by weight" (claims 12, 18, 24 and 27), "from about 30 to about 100% by weight" (claims 13 and 19), "from about 60 to about 100% by weight" (claims 25 and 28) and "about 85% by weight" (claims 14 and 20).

The compositions of Breivik et al. may contain EPA and DHA in relative amounts of from 1:2 to 2:1 (col. 2, line 53) and the EPA and DHA may be present in the form of

an ester (col. 12, lines 31-34 and 40-44). An example of an EPA:DHA proportion of the present claims is 2:1. In particular, claim 35 sets forth that "the EPA content of the EPA + DHA mixture is from about 40 to about 60% by weight and the DHA content of the EPA + DHA mixture is from about 25% to about 45% by weight". Thus, claim 35 provides for an EPA/DHA mixture where the EPA content is 50% of the EPA/DHA mixture and the DHA content of the EPA/DHA mixture is 25% and this simplifies to 2:1, i.e., a proportion expressly taught by Breivik et al. In the Example at col. 11, the patentees show a pharmaceutical composition containing 525 mg/capsule of EPA ethyl ester and 315 mg/capsule of DHA ethyl ester which equates to an EPA:DHA ratio of 1.66:1.

Breivik et al. further teach that *generally*, for the average adult person the doses may vary from 1.0 to 10 grams, i.e., of the EPA/DHA mixture, depending on body size and the seriousness of the condition to be treated (col.10, lines 43-46). Present claims 16 and 22 set forth that the dosage is "from about 0.7 to about 1.5g daily".

The compositions can be used for the multiple risk factors for cardiovascular diseases (see the abstract). Breivik et al. further teach that "cardiovascular diseases leading to morbidity and premature mortality is related to several risk factors such as hypertension, hypertriglyceridemia, hypercholesterolemia, high blood platelet aggregation..." (col. 1, lines 14-20) and that their compositions have an advantageous effect for such risk factors (col. 2, lines 50-58), including a synergy between EPA and DHA (col. 2, lines 65-67).

The difference between the above and the claimed subject matter lies in that Breivik et al. do not expressly disclose that the "cardiovascular diseases" in the

expression "treatment or prophylaxis of multiple risk factors for cardiovascular diseases" (see the last sentence of the abstract, for example) include myocardial infarction or that the patient being treated has already had a "cardiovascular event", e.g., present claim 12, including a myocardial infarction, e.g., claim 18.

However, the difference between the subject matter sought to be patented and the prior art is clearly such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because Breivik et al. expressly teach that the risk factors leading to a cardiovascular disease which causes premature mortality can be reduced and thus, one of ordinary skill in the art would have appreciated that incidence of the cardiovascular disease, including myocardial infarction, itself could be reduced. Also, because the patentees fail to particularly limit their teachings as to whether the cardiovascular disease has occurred previously or not in the patient, it is reasonable to interpret the teachings to include not only instances where the cardiovascular disease may occur for the first time in a patient, but also those instances of *re*occurrence as is presently claimed.

The selection of any specific patient population in whom to practice such a reduction in the incidence of risk factors for a cardiovascular disease, such as a patient who has suffered a myocardial infarction, would have been a matter well within the purview of the skilled artisan. The skilled artisan would have been motivated to select the presently claimed patients, i.e., myocardial infarction survivors, because not only were such patients known to one of ordinary skill in the art (see Harrison's at page 1066, col. 1, first paragraph "Although survival following hospitalization has improved over the

last two decades, an additional 5 to 10 percent of survivors die in the first year following myocardial infarction and the number of myocardial infarctions each year in the United States has remained largely unchanged since the early 1970s. Risk of excess mortality and recurrent nonfatal myocardial infarction persists in patients who recover."), but the cardiovascular disease risk factors identified and effectively treated by of Breivik et al. include those risk factors known to be associated with myocardial infarction. In particular, Breivik et al. expressly disclose that the composition is effective against hypertension and elevated serum cholesterol levels (col. 1, lines 14-20; col. 6, lines 20-27; col. 8, lines 25-30 and col. 9, lines 19-24) while Harrison's teaches that damage associated with myocardial infarction "is produced or facilitated by factors such as cigarette smoking, hypertension and lipid accumulation" (page 1066, col. 1, near the beginning of the second paragraph). Therefore, it would have been appreciated by one of ordinary skill in the art that a patient who has suffered from, or is at risk for developing a myocardial infarction, was contemplated by Breivik et al. for treatment. Also, because one of ordinary skill in the art would have been dedicated to the preservation of health and life, such a person would have clearly been motivated to reduce the incidence of occurrence or reoccurrence of any disease, including a cardiovascular disease such as myocardial infarction.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none are allowed.

None of the claims are allowed.

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

May 14, 2005